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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,024	02/23/2004	Veli-Matti Lehtola	13601-016	3763

757 7590 10/05/2009

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,024	LEHTOLA ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,24 and 27-39* is/are pending in the application.

4a) Of the above claim(s) *10,12-20 and 35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11, 24, and 27-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' response to restriction requirement, which was filed on 15 May 2009.

* * * * *

Election/Restrictions

Applicants' election without traverse of Group I and species (b) wet granulation (claim 11) in the reply filed on 15 May 2009 is acknowledged.

Claims 10 and 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 May 2009.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 34 recites two different formulations; one formulation produced by a granulation method and another formulation produced by a direct compression method. It is unclear if applicants are claiming the granulation formulation, the direct compression formulation, or both. Clarification is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-9, 11, 24, and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Application No. 2005/0215528 ("Furuya").

Furuya discloses a pharmaceutical composition comprising selective estrogen receptor modulator (SERM) drugs (*see* paragraph 0006). The disclosed composition is comprised of:

- the solid drug formulation of instant claim 1 (*see* paragraph 0070);
- the granulates of instant claim 1 (*see* paragraph 0447);
- the compound of formula 1 (*see* paragraph 0125);
- the intra-granular excipients of instant claim 1 (*see* paragraph 0449);
- the disintegrant of instant claim 1 (*see* paragraph 0448);
- the ospemifene of instant claim 2 (*see* paragraph 0125);
- the carboxymethylcellulose of instant claims 3 and 24 (*see* paragraph 0452);
- the diluent (lactose) of instant claims 4 and 25 (*see* paragraph 0070);
- the binder of instant claims 5 and 26 (*see* paragraph 0448);
- the excipient combination of instant claims 6 and 27(*see* paragraph 0448);
- the carboxymethylcellulose of instant claims 7 and 28(*see* paragraph 0452);

- the lactose of instant claims 8 and 29 (*see* paragraph 0070);
- the dextrin of instant claims 9 and 30 (*see* paragraph 0451);
- the pregelatinized starch (starch) of instant claims 33 and 34 (see paragraph 0449);
- the maize starch (corn starch) of instant claims 33 and 34 (see paragraph 0449); and
- the magnesium stearate of instant claims 33 and 34 (see paragraph 0450).

The wet granulation process disclosed in claim 11 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In any event, Furuya discloses a wet granulation process (*see* paragraphs 0494 and 0515).

Furuya is silent with respect to dissolution profiles. Applicants' composition, as claimed, is the same as the prior art. As, claimed, applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594.

In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

Furuya explains that the disclosed composition is beneficial as a "…preventative or therapeutic method capable of improving preventative or therapeutic effect of a GnRH agonist on various diseases…" *See* paragraph 0003.

While Furuya does not explicitly teach the ratios of particle sizes and active ingredient concentration range of instant claim 1 or the disintegrant concentration range of instant claims 7 and 28, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine suitable particle size ratios through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Furuya discloses: (a) microcapsule formulations (*see* paragraph 0468) within the size range claimed in instant claim 1, i.e. as small as 2 μm (*see* paragraph 0085); (b) an active ingredient concentration range within the claimed range of instant claim 1 (*see* paragraph 0495); and (c) a disintegrant concentration range within the claimed range of instant claim 7 (*see* paragraph 0512).

Moreover, generally, differences in particle size ratios and concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a granulate formulation comprising ospemifiene, as taught by Furuya. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful as a preventative or therapeutic method, as explained by Furuya.

*

2. Claims 1-9, 11, 24, and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Application No. 2005/0215528 (“Furuya”) in view of US Application No. 2003/0162761 ("Steiner").

Furuya is discussed above.

Furuya differs from the instant application in that it does not teach some of the excipients listed in claims 33 and 34, such as povidone and sodium starch glycolate.

Steiner teaches formulations comprising, e.g., a selective androgen receptor modulator compound in combination with a selective estrogen receptor modulator (see paragraph 0121). The formulation may be comprised of granules (see paragraph 0076) and may contain excipients such as povidone and sodium starch glycolate (see paragraph 0085).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a granulate formulation comprising ospemifiene, with excipients such as povidone and sodium starch glycolate as taught by Furuya in view of Steiner. One of ordinary skill in the art at the time the invention was made would have

been motivated to make such a composition because it is useful as a preventative or therapeutic method, as explained by Furuya.

* * * * *

Response to Arguments

Applicants' arguments filed 3 February 2009 have been fully considered but they are not persuasive.

1. Applicants argue that Examiner has not viewed applicants' invention "as a whole". See remarks, pages 9-10.

Examiner respectfully disagrees. Independent claim 1 recites a solid drug formulation comprising 30 to 90 mg of ospemifine in combination with one or more intra-granular excipients, wherein at least one intra-granular excipient is a disintegrant. Furuya teaches a formulation which may comprise granulates (see paragraph 0447). The active ingredient may be ospemifine (see paragraph 0125) in a concentration of 30-70%, which overlaps with the 30-90% of instant claim 1. The formulation may contain a disintegrant (see paragraph 0448). Thus, Furuya explicitly suggests each element of independent claim 1. As such, examiner respectfully submits that the 35 USC 103 rejection is proper.

2. Applicants argue that the disclosed formulation shows unexpected disintegration times as compared with ospemifine tablets made by direct compression. See remarks, page 11.

Examiner respectfully submits that Furuya, like applicants, teach the use of wet granulation techniques to formulate their composition (see paragraphs 0494 and 0515).

Since Furuya teaches a formulation comprising the same ingredients as instant claim 1 in the same concentration as instant claim 1, in the same configuration as instant claim 1, and using the same formulation method as is disclosed in the instant specification, the properties of the two compositions are expected to be the same.

3. Applicants argue that the rule of In re Aller does not apply to the instant case. See remarks, pages 11-12.

Examiner respectfully submits that Furuya teaches overlapping concentration ranges with respect to both the active ingredient (see paragraph 0495), i.e. 30 to 70% and with respect to the disintegrant (see paragraph 512), i.e. 0.5 to 15%. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

* * * * *

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615